

UNITED STATES DISTRICT COURT

for the

Eastern District of Michigan

United States of America

v.

ZEINAB MAKKI
a.k.a. ZAINAB MAKKI

Case: 2:22-mj-30141

Assigned To : Unassigned

Assign. Date : 3/17/2022

Case No. Description: RE: SEALED MATTER
(EOB)

CRIMINAL COMPLAINT

I, the complainant in this case, state that the following is true to the best of my knowledge and belief.

On or about the date(s) of January 2, 2012 thru March 16, 2022 in the county of WAYNE COUNTY in the
EASTERN District of MICHIGAN, the defendant(s) violated:*Code Section**Offense Description*

18 U.S.C. § 1347

Health Care Fraud

This criminal complaint is based on these facts:

SEE AFFIDAVIT.

☒ Continued on the attached sheet.Sworn to before me and signed in my presence
and/or by reliable electronic means.Date: March 17, 2022City and state: Detroit, Michigan
Complainant's signature

Special Agent MICHAEL PEMBERTON, HHS-OIG

Printed name and title


Judge's signature

HON. DAVID R. GRAND, United States Magistrate Judge

Printed name and title

AFFIDAVIT IN SUPPORT OF A COMPLAINT

I, Michael Pemberton, Special Agent of the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG) being duly sworn, state that:

INVESTIGATION INTRODUCTION AND AGENT BACKGROUND

1. I am an investigative or law enforcement officer of the United States within the meaning of Section 2510(7) of Title 18 of the United States Code. I am empowered to conduct investigations of and to make arrests for offenses enumerated in Title 18 of the United States Code.

2. I have been employed by the HHS-OIG as a Special Agent since June 2015. I previously worked as a Special Agent with the Air Force Office of Special Investigations (AFOSI) and Environment Protection Agency, Criminal Investigation Division (EPA-CID). I have conducted criminal investigations as a Special Agent since 2002. During my employment with the HHS-OIG, I have investigated federal crimes including health care fraud, wire fraud, controlled substance diversion, and various other criminal matters. At all times during the investigation described in this affidavit, I have been acting in an official capacity as a Special Agent of the HHS-OIG.

3. This affidavit is made in support of a criminal complaint and arrest warrant charging ZEINAB MAKKI (AKA ZAINAB MAKKI) with committing health care fraud in violation of Title 18, United States Code, Section 1347.

4. This affidavit is submitted for the limited purpose of securing a criminal complaint and arrest warrant; therefore, this affidavit does not contain every fact that I have learned during the course of the investigation. I have only set forth the facts necessary to establish probable cause to believe that ZEINAB MAKKI, a pharmacist licensed to practice in Michigan, violated the above-identified statute. The information contained in this affidavit is based upon my personal knowledge, training and experience, as well as the combined knowledge, training and experience of other law enforcement officers and agents with whom I have had discussions.

5. 18 U.S.C. §1347 makes it unlawful to knowingly and willfully execute or attempt to execute a scheme or artifice to defraud any health care benefit program; or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program.

DEFENDANT AND AFFILIATED PHARMACIES

6. ZEINAB MAKKI (DoB: XX/XX/1963) is a resident of Dearborn Heights, Michigan, and is a licensed pharmacist in the State of Michigan under the name Zainab Makki. Her license was issued on August 9, 1988, and is set to expire on August 9, 2022.

7. New Millennium Drugs (NMD) was registered as a limited liability corporation in the State of Michigan with a business address in Inkster, MI.

8. Western Wayne Pharmaceuticals (WWP) is registered as a limited liability corporation in the State of Michigan with a business address in Inkster, MI.

9. According to the website of the Michigan Department of Licensing and Regulatory Affairs (LARA), ZEINAB MAKKI was identified as the pharmacist-in-charge at NMD beginning December 20, 2001 and was the pharmacist-in-charge at WWP, beginning November 14, 2017.

10. My review of records received from PBMs also indicates ZEINAB MAKKI was the pharmacist-in-charge for both NMD and WWP. Additionally, ZEINAB MAKKI identified herself as the pharmacist-in-charge during pharmacy audits by PBMs and state agencies, and she was described as the main pharmacist at NMD and WWP by multiple witnesses I interviewed. According to the State of Michigan (Mich. Comp. Laws § 333.17748), the pharmacist-in-charge “shall supervise the practice of pharmacy for the pharmacy.” These duties include the “establishment and supervision of the record-keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs and devices.”

11. ZEINAB MAKKI was the pharmacist-in-charge at NMD from 2001 until January 28, 2021, when the pharmacy was sold; and at WWP from November 2017 to present.

12. ZEINAB’S MAKKI’s husband, Wahid Makki, owned NMD and WWP during the relevant periods.

THE MEDICARE AND MEDICAID PROGRAMS

13. The Medicare Program (“Medicare”) is a federally funded health care program providing benefits to persons who are sixty-five years of age or older or disabled. Medicare is administered by the Centers for Medicare & Medicaid Services (CMS), a federal agency within the Department of Health and Human Services (“HHS”). Individuals who receive Medicare benefits are referred to as Medicare “beneficiaries.”

14. Medicare is a “health care benefit program,” as defined by 18 U.S.C. § 24(b). Medicare has four parts: hospital insurance (Part A), medical insurance (Part B), Medicare Advantage (Part C), and prescription drug benefits (Part D). Medicare Part D subsidized the cost of prescription drugs for Medicare beneficiaries in the United States. Generally, Medicare Part D covers part or all of the costs of prescription drugs properly dispensed to a Medicare beneficiary if, among other requirements, the prescription drugs were medically necessary and ordered by a physician. This investigation involves Medicare Part D, prescription drug benefits, and prescriptions paid for by Medicaid.

15. A pharmacy can participate in Medicare Part D by entering into a retail network agreement directly with a plan or with one or more Pharmacy Benefit Managers (“PBMs”). A PBM acts on behalf of one or more Medicare drug plans. Through a plan’s PBM, a pharmacy can join the plan’s network. When a Medicare

Part D beneficiary presents a prescription to a pharmacy, the pharmacy submits a claim either directly to the plan or to a PBM that represents the beneficiary's Medicare drug plan. The plan or PBM determines whether the pharmacy is entitled to payment for each claim and periodically pays the pharmacy for outstanding claims. The drug plan's sponsor reimburses the PBM for its payments to the pharmacy.

16. CVS Caremark, OptumRx, and Express Scripts are three of several PBMs. CVS Caremark processes and adjudicates claims electronically in Arizona. OptumRx and Express Scripts process and pays claims via interstate wire.

17. Medicare, through CMS, compensates the Medicare drug plan sponsors and pays the sponsors a monthly fee for each Medicare beneficiary of the sponsors' plans.

18. Enrolled Medicare providers agree to abide by the policies and procedures, rules, and regulations governing reimbursement. Medicare providers agree to comply with all Medicare-related policies and procedures including a certification to not knowingly submit or cause to be submitted false and fraudulent claims. To receive Medicare funds, enrolled providers, together with their authorized agents, employees, and contractors, are required to abide by all the provisions of the Social Security Act, the regulations promulgated under the Act,

and applicable policies and procedures, rules, and regulations, issued by CMS and its authorized agents and contractors.

19. Qlarant is the Medicare Part C and Part D program integrity contractor for CMS under the National Benefit Integrity (NBI) Medicare Drug Integrity Contract (MEDIC). The purpose of Qlarant is to detect, prevent, and investigate allegations of fraud, waste, and abuse in the Part C (Medicare Advantage Organizations) and Part D (Prescription Drug Coverage) programs on a national level.

20. The Michigan Medicaid Program (“Medicaid”) is a federal and state funded health care program providing benefits to individuals and families who meet specified financial and other eligibility requirements, and certain other individuals who lack adequate resources to pay for medical care. CMS is responsible for overseeing the Medicaid program in participating states, including Michigan. Individuals who receive benefits under the Medicaid program are also referred to as “beneficiaries.”

21. Medicaid covers the costs of medical services and products ranging from routine preventive medical care for children to institutional care for the elderly and disabled. Among the specific medical services and products provided by Medicaid are reimbursements to pharmacies for properly dispensed prescription

drugs. Generally, Medicaid covers these costs if, among other requirements, they are medically necessary and ordered by a physician.

22. NMD and WWP were enrolled as pharmaceutical providers with Medicaid and Medicare Part D Plan Sponsors. An enrolled provider is permitted to submit claims to a Medicaid and a Medicare Part D Plan Sponsor for payment.

23. NMD and WWP electronically submitted, through interstate wires, health care claims to PBMs containing, among other data, patient identifying information, drug names, and the quantities purportedly dispensed. Medicare and Medicaid's reimbursement for these claims were sent by PBMs to the pharmacies' bank accounts via electronic funds transfer.

PROBABLE CAUSE FOR ARREST

24. ZEINAB MAKKI submitted or caused to be submitted false and fraudulent claims on behalf of NMD and WWP through interstate wires to Medicare, Medicaid, and other insurers, through a common pharmacy fraud scheme known as a shortage scheme. In a shortage scheme, a pharmacy submits claims to Medicare, Medicaid, and other health insurers for medication that the pharmacy does not dispense to patients. ZEINAB MAKKI submitted claims electronically to PBMs, including Medicare, CVS Caremark, OptumRx, and Express Scripts among others. The submission of claims caused health insurers to make payments to the pharmacies operated by ZEINAB MAKKI. An audit of these claims submitted by ZEINAB

MAKKI found that ZEINAB MAKKI submitted or caused to be submitted at least \$10.6 million in false and fraudulent claims to Medicare and Medicaid.

25. Beginning in or around 2012, and continuing to the present date, in Wayne County, in the Eastern District of Michigan, ZEINAB MAKKI, as specified below, did knowingly and willfully execute, and attempt to execute, a scheme and artifice to defraud health care benefit programs affecting commerce, as defined in Title 18, United States Code, Section 24(b), that is, Medicare, Medicare drug plan sponsors, Medicaid, and Medicaid health plans, and to obtain, by means of materially false and fraudulent pretenses, representations, and promises, money and property owned by, and under the custody and control of, said health care benefit programs, in connection with the delivery of and payment for health care benefits, items, and services.

PURPOSE OF THE SCHEME AND ARTIFICE

26. It was the object and purpose of the scheme and artifice for ZEINAB MAKKI to unlawfully enrich herself by, among other things: (a) submitting or causing the submission of false and fraudulent claims for drugs that were not dispensed; (b) submitting or causing the submission of false and fraudulent claims for drugs that were dispensed to deceased beneficiaries; (c) submitting or causing the submission of false and fraudulent claims for larger quantities of drugs than were actually dispensed; (d) submitting or causing the submission of false and fraudulent

claims for dispensing drugs without a valid prescription; and (e) diverting fraud proceeds for her personal use and benefit.

U.S. HHS-OIG INVESTIGATION

27. On December 27, 2019, I initiated a criminal investigation into ZEINAB MAKKI based on a Medicaid drug shortage scheme at NMD during 2012 to 2014, uncovered by the State of Michigan's HHS-OIG. During my investigation, I interviewed several witnesses who confirmed ZEINAB MAKKI's role as the pharmacist-in-charge at NMD and WWP, as well as her active participation in the submission of claims for pharmaceuticals. PBM records reflect ZEINAB MAKKI was also directly involved with pharmacy audits, including providing information regarding pharmaceutical purchases to auditors performing invoice reviews.

28. As part of my investigation, I obtained drug invoice data from pharmaceutical wholesalers used by NMD, where ZEINAB MAKKI was the pharmacist-in-charge, from 2012 to October 2020 and requested an invoice review by Qlarant. Qlarant compared NMD's Medicare and Medicaid claims data to the drug purchase histories for NMD for the period January 2, 2012 – October 9, 2020. This review included all drugs claimed and billed by NMD during the period. Qlarant's comparison revealed that NMD with ZEINAB MAKKI as the pharmacist-in-charge submitted, and caused the submission of, false and fraudulent claims to Medicare, Medicare drug plan sponsors, Medicaid, and Medicaid health plans on

behalf of NMD for drugs purportedly dispensed, in quantities that exceeded the amount NMD actually purchased from pharmaceutical wholesalers.

29. A review of Medicare Part D claims data also established that NMD submitted a total of 277 claims (for medication) for beneficiaries who were deceased prior to the purported service date. Medicare and Medicaid paid NMD \$14,379.16 for these claims. Based upon my review of State of Michigan Unemployment records, ZEINAB MAKKI was the only pharmacist-in-charge with earnings reported at NMD during the timeframe that claims data reflects these medications were purportedly dispensed to the dead beneficiaries. Though at least one pharmacist filled in at NMD part time, ZEINAB MAKKI was the primary pharmacist, as corroborated by the unemployment records.

30. During my investigation, I also requested and received records from multiple PBMs who were contracted with NMD. Some of the records I obtained included PBM audits wherein copies of prescriptions and labels were provided to auditors by NMD. These prescription labels were generated by NMD's pharmacy system and have the initials of the pharmacist and/or pharmacy technician who processed the audited prescriptions. In my review of the copied prescription labels for NMD, I saw the initials "ZM" on many labels for PBM audits performed in 2012, 2013, 2015, and 2017. I also reviewed prescription labels from WWP, which were provided to me by LARA. Most of these prescription labels also had the initials

“ZM” on them. I believe the initials “ZM” refer to pharmacist-in-charge ZEINAB MAKKI. The presence of ZEINAB MAKKI’s initials on prescription labels throughout the relevant period indicates her direct involvement in the processing of prescriptions and the submission of health care claims for NMD and WWP. Additionally, several of these audits had findings that included drug invoice shortages, overbilled quantities, altered prescriptions without appropriate documentation, incorrect prescriber billed/inappropriate use of prescriber ID, missing hardcopy prescriptions, and missing signature logs.

31. As part of my investigation, I also obtained drug invoice data from pharmaceutical wholesalers used by WWP from November 10, 2016 through October 9, 2020. ZEINAB MAKKI was involved at WWP pharmacy since the pharmacy opened and she was the pharmacist-in-charge from November 14, 2017 to present. ZEINAB MAKKI was the pharmacist-in-charge over the vast majority of Qlarant’s review period. I requested an invoice reconciliation by Qlarant. Qlarant’s comparison revealed that WWP, with ZEINAB MAKKI as pharmacist-in-charge submitted, and caused the submission of, false and fraudulent claims to Medicare, Medicare drug plan sponsors, Medicaid, and Medicaid health plans on behalf of WWP for drugs purportedly dispensed, in quantities that exceeded the amount WWP actually purchased from pharmaceutical wholesalers.

STATE OF MICHIGAN-LARA INVESTIGATION

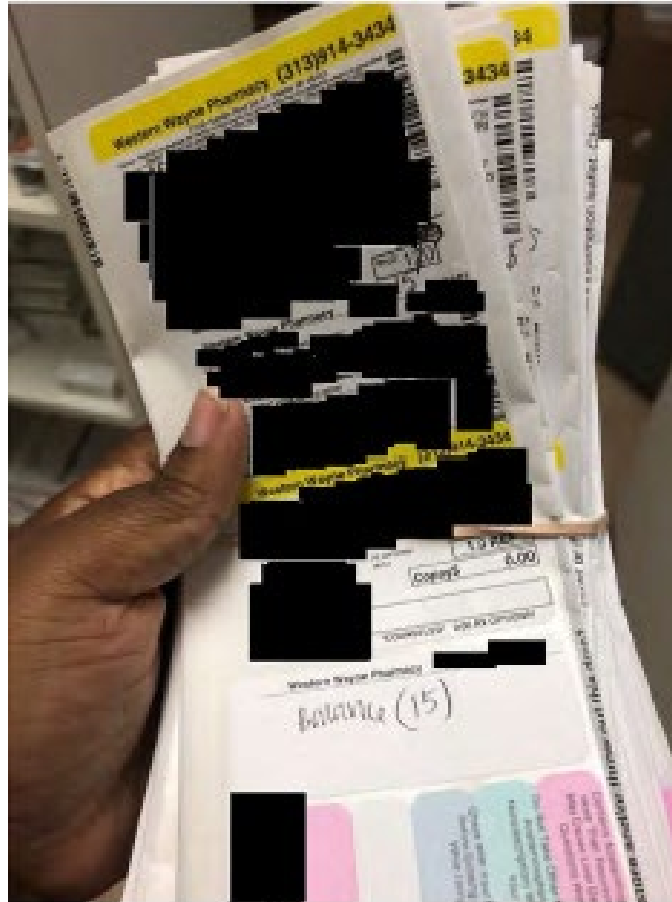
32. On June 25, 2021, LARA opened an investigation into ZEINAB MAKKI based on allegations which included that ZEINAB MAKKI was fraudulently billing for controlled substances as the pharmacist-in-charge at WWP. I received a copy of LARA's investigative file regarding ZEINAB MAKKI on January 6, 2022.

33. During LARA's investigation, an inspection was performed at WWP on September 9, 2021. As a result of the inspection, LARA became concerned that ZEINAB MAKKI was engaging in health care fraud at WWP, for fraudulently submitting claims for larger quantities of drugs than had actually been dispensed. During the inspection, the investigator recovered a large number of prescription labels that were annotated with an amount that was "owed" to the beneficiary, indicating the medication was partially dispensed to the beneficiary. Crossing out full quantities on printed labels with the amounts changed in handwritten ink to a lower quantity is an indication the pharmacy did not have enough inventory to dispense the full amount at the time the claims were submitted to insurance.

34. According to 2015 pharmacy guidance for Medicaid on the CMS website (CMS.gov), "Adjudicate partial fills appropriately. Do not 'owe' patients any drug quantity if the full quantity to be dispensed has already been billed." The guidance further states "Consider the risk for fraud, waste, or abuse if pharmacy staff members bill for the entire prescribed quantity but dispense a partial supply while

waiting for additional stock to be delivered. A partial fill occurs when a pharmacy does not dispense the total quantity of the medication indicated on the prescription. Potential fraud exists because the pharmacy may receive reimbursement to which it was not entitled. If the pharmacy bills and receives reimbursement for a complete fill and ‘owes’ the beneficiary the remainder of the fill, the beneficiary may not pick up the owed portion, or the pharmacy may not be able to obtain additional supply of the medication. When the medication is returned to stock, the pharmacy inventory is inaccurate, and Medicaid has overpaid the pharmacy.”

35. The labels recovered from WWP with the annotation for owed amounts pertained to claims submitted or caused to be submitted by ZEINAB MAKKI to Medicaid between February and August 2021. Though many of these labels were generated multiple months prior to the inspection, there were no annotations/markings written on the labels indicating the owed balances had ever been filled. Most of the prescription labels provided by LARA had the initials “ZM” on them, which appears to refer to pharmacist-in-charge ZEINAB MAKKI. See Exhibit One (a photograph of an “owe” label recovered by LARA investigators at WWP).



36. During the interview, ZEINAB MAKKI claimed to the LARA investigator that these labels were just kept for her records; however, as the LARA investigator noted in their report, maintaining labels marked with owed quantities is not standard pharmacy practice. The labels are an indication of health care fraud as the report states, “where the licensee [ZAINAB MAKKI] charges for a full quantity dispensed, but only dispenses a partial quantity, or none at all.”

37. Routinely billing full prescriptions while only dispensing a partial amount or no medication is fraud and can lead to the type of drug shortage alleged in this scheme. Pharmacies are required to bill for what is dispensed to beneficiaries

and claims for medication that are not dispensed must be reversed, generally within two to three weeks. When claims for medication not dispensed do not get reversed by a pharmacy, it often will lead to a deficit of pharmaceuticals purchased for which claims were paid by health insurers.

38. Another instance of ZEINAB MAKKI billing for larger quantities of medication than dispensed pertained to medication placed in blister packaging for beneficiaries residing in adult foster care homes. During the LARA inspection, the investigator observed blister packets for which claims had been submitted to Medicaid. The inspector noticed the number of tablets/pills in the blister packs was less than the amount billed and contained on the prescription label. The quantity on the prescription label was 62, however, the blister pack only contained 60 pills. See Exhibit 2 (a month's supply, in two blister packs of Clonazepam for Medicaid beneficiary J.T.). A review of Medicaid claims data revealed that ZEINAB MAKKI submitted claims or caused the submission of claims to Medicaid asserting WWP dispensed 62 pills to Medicaid beneficiary J.T. monthly from July 2019 through January 2022. Routinely billing for quantities higher than dispensed to beneficiaries can also lead to the type of drug shortage alleged in this scheme, especially when it is a broader practice involving many beneficiaries, month after month. I reviewed Medicare claims data for NMD and WWP and found similar billing patterns, where

quantities of certain drugs that were billed exceeded the number of days in that month.



39. The LARA investigation also revealed that ZEINAB MAKKI was submitting claims or caused the submission of claims to Medicaid for medication dispensed without a valid prescription. A review of the Michigan Automated Prescription Systems (MAPS) data revealed that Lorazepam and Clonazepam prescriptions were issued for multiple Medicaid beneficiaries by Dr. T.I., and were purportedly dispensed by WWP. The data indicated Dr. T.I. purportedly wrote Lorazepam prescriptions for beneficiaries M.D. and J.B., and Clonazepam prescriptions for beneficiaries A.B. and M.H., and that these were purportedly

dispensed by WWP. Lorazepam and Clonazepam are DEA Schedule IV controlled substances.

40. The LARA investigator contacted Dr. T.I.'s office to check the validity of the Lorazepam and Clonazepam prescriptions. Dr. T.I.'s office informed LARA that Dr. T.I. did not have any record of a Lorazepam prescription for M.D.; Dr. T.I. did not have any record of a Lorazepam prescription for J.B.; Dr. T.I. did not have any record of a Clonazepam prescription for A.B.; and Dr. T.I. did not have any record of a Clonazepam prescription for M.H.

41. Medicaid reimbursed WWP for the Lorazepam and Clonazepam medications the pharmacy dispensed based on prescriptions that the office staff of the purported prescriber denied s/he wrote. Billing insurance for fictitious prescriptions is fraud. The reimbursements were deposited into bank accounts controlled by Wahid Makki and used by both ZEINAB MAKKI and Wahid Makki.

42. I reviewed an April 26, 2006, complaint against ZEINAB MAKKI's pharmacist license that alleged multiple prescriptions were improperly dispensed to a patient of NMD in March and April 2005. The complaint stated, "(t)he dispensing pharmacist(s) did not have an original Board-approved prescription for any of the medications, failed to initial the prescription record, and remain unidentified." The Board of Pharmacy imposed a \$500 fine and a 2-year term of probation on ZEINAB MAKKI as a result of this violation.

REVIEW OF FINANCIAL RECORDS

43. According to bank records, NMD received at least \$33 million in reimbursements from PBMs between January 2013 and January 2021 into an NMD account that is in held in the name of Wahid Makki for claims submitted or cause to be submitted to Medicare by ZEINAB MAKKI. Approximately \$984,599 was transferred from the NMD account into personal accounts held in the names of ZEINAB MAKKI or both ZEINAB MAKKI and Wahid Makki.

44. According to bank records, WWP received approximately \$7.7 million in reimbursements from PBMs between July 2016 and August 2021 into a WWP account that is in held in the name of Wahid Makki and lists ZEINAB MAKKI as a co-signor, for claims that were submitted or caused to be submitted to Medicare and Medicaid by ZEINAB MAKKI. Of this amount, ZEINAB MAKKI transferred approximately \$450,000 to a personal account in her name.

CONCLUSION

45. Your affiant submits that there is probable cause to believe that ZEINAB MAKKI devised and perpetrated a scheme or artifice to defraud federal health care programs. In furtherance of and to execute this scheme, ZEINAB MAKKI sent electronic health care claims in interstate commerce by means of wire communication, as set forth above.

46. Therefore, your affiant believes that probable cause exists that ZEINAB MAKKI violated 18 U.S.C. §1347 (health care fraud).



MICHAEL A. PEMBERTON
Special Agent
HHS-OIG

Sworn to before me and signed in my
presence and/or by reliable electronic means.



HON. DAVID R. GRAND
United States Magistrate Judge

Dated: March 17, 2022